

COVID-19 Vaccine Quick Facts

- Safe, effective COVID-19 vaccines will be available soon to help us defeat this virus, regain control of our lives and get back to the people and places we love.
- Although the vaccines were developed quickly, they were built on years of work in developing vaccines for similar viruses. This allowed for rapid development without cutting corners.
- Because developing a COVID-19 vaccine was so important, several manufacturers and the U.S. Food and Drug Administration all placed it as their highest priority, which allowed them all to focus attention on the vaccine.
- More than 70,000 people participated in clinical trials for two vaccines to see if they are safe and effective. To date, the vaccines are nearly 95% effective in preventing COVID-19 with no major safety concerns from people in the trials, manufacturers or the FDA.
- There is no COVID-19 virus in the vaccine. The vaccine imitates the infection so that our bodies think a germ like the virus is attacking. This creates the antibody defenses we need to fight off COVID-19 if or when we come into contact with the real germ later on
- Some people may have mild temporary reactions for a day or two after being vaccinated, but those reactions are usually minor and can include swelling where the injection was given, tiredness, or feeling "off."
- In a few months, these tested, safe and effective vaccines will be available to everyone who wants
 to receive them, but supplies will be limited at first. Independent state and federal public health
 advisory groups have determined that the best way to fight COVID-19 is to start first with
 vaccinations for those most at risk, then reach more people as the vaccine supply increases
 throughout 2021.

Are there vaccines that might be safe and work in preventing COVID-19?

Yes. As of November 30, 2020, there are two vaccines that are at the end of the last phase of testing in clinical trials with promising results. One is from Pfizer and one is from Moderna. Trial results so far show the Pfizer vaccine is 95% effective and the Moderna vaccine is 94.5% effective in preventing COVID-19 with no safety concerns. There are still other vaccines that are in the development stage, including one from AstraZeneca, and those are also expected to be safe and effective.

For some vaccines, as is the case for the first two that are becoming available, two shots will be needed a number of days apart, as the second dose will boost immunity.

Who verifies that the vaccines are safe and can prevent COVID-19?

The U.S. Food and Drug Administration (FDA) is responsible for making sure all vaccines are safe and effective and has a longstanding process for ensuring this is true for all vaccines, not just COVID-19. The COVID-19 vaccines must go through and pass clinical trials like other drugs and vaccines. Because the FDA made COVID-19 vaccine development such a priority, it gave the vaccine priority for review. This review allowed the FDA to do what is called an Emergency Use Authorization, which allows manufacturers to get the vaccine to the public faster, as long as the vaccines are found to be safe and effective and then verified by an independent committee. It does not allow manufacturers or the FDA to skip any steps. The FDA simply speeds up the process by clearing the way for the COVID vaccine to move to the front of the line in every phase of development and testing.

What is an Emergency Use Authorization (EUA)?

An Emergency Use Authorization (EUA) is issued by the FDA during a public health emergency to allow for the use of new medical products, such as a vaccine, more quickly, but only if research data proves that a vaccine is safe and that it can prevent disease. While the FDA is speeding up the approval process for COVID vaccines, it does not skip any steps; it clears the way for the COVID vaccine to move to the front of the line in every phase of development and testing.

An independent advisory committee also reviews the vaccine testing data before issuing an EUA for a COVID-19 vaccine. The advisory group has no ties to any company, political administration or individual, and its meetings and findings are open to the public. Information about upcoming meetings is posted by the <u>FDA</u>. Pfizer applied for an EUA on November 20, 2020, and the advisory committee approved it on December 10, 2020. Moderna applied for an EUA on November 30, 2020, and the advisory committee will meet on December 17, 2020.

What happens after an EUA is issued?

The Center for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices will review the data and recommend who should be vaccinated based on clinical trial results. This ensures that the vaccine is safe and effective for those who get it.

How much vaccine will be distributed?

Once a vaccine is authorized for use by the FDA, states will only receive very limited supplies at first. The federal government will determine the number of COVID-19 vaccines each state will receive. The amount of vaccine sent to states will be based on the size of the state's population.

Who will be vaccinated first?

Independent state and federal public health advisory groups have determined that the best way to fight COVID-19 is to first start with vaccinations for those most at risk, then reach more people as the vaccine supply increases from January 2021 to June 2021.

In North Carolina, the initial supply of vaccines will go to a small number of hospitals to vaccinate health care workers at high risk of exposure to COVID-19, especially those who are caring for patients with COVID-19 or cleaning areas used by patients with COVID-19. Because of the limited initial vaccine supply, not all hospitals will receive vaccines at first. As more vaccine becomes available, it will be distributed to more of the state's hospitals and to local health departments to focus on vaccinating high-risk health care workers.

Long-term care staff and residents are also one of the earliest groups who will receive a vaccine. Giving vaccinations at nursing homes, most adult care homes and other long-term care settings is being managed by the federal government. However, the vaccines used in long-term care will come from North Carolina's supply.

We hope that by early 2021, health departments, community health centers and other local healthcare partners will start vaccinating other adults who are at high risk for complications. Being high risk means they have two or more chronic conditions identified by the CDC that put them at higher risk for complications from exposure.

As the vaccine becomes more broadly available, it will be offered in a variety of settings to all adults who want one, including clinics and pharmacies.

Will children receive the vaccine?

While clinical trials have shown safety and effectiveness for adults, children will not receive vaccines until clinical trials with children are completed to ensure safety and effectiveness.

How will the vaccine be shipped?

The federal government is coordinating the shipment of vaccines and vaccination supply kits to states. Vaccines will be shipped to states as soon as they receive FDA authorization so that states have supplies ready to use as soon as the CDC Advisory Committee on Immunization Practices recommends who should receive the vaccine.

How will the vaccine be stored?

Eleven hospital sites across North Carolina have been identified as locations with the greatest capacity for ultra-cold storage for the anticipated Pfizer vaccine, which will come out first. Vaccines that require ultra-cold storage will come with packaging and cooling material to meet the storage requirements for sites that do not have permanent ultra-cold storage. The Moderna vaccine does not require ultra-cold storage. The state and CDC will deliver training on COVID-19 vaccine storage, handling and administration based on federal recommendations and product information from vaccine manufacturers. As more vaccines are ready for use, storage and usage requirements will be developed for vaccinators to use.

How will staff and residents in long-term care facilities be vaccinated?

The federal government is managing vaccinations for most staff and residents of long-term care facilities; however, those doses will come from the state's allotment. Long-term care facilities include skilled nursing facilities, adult care homes, family care homes, group homes and intermediate care facilities for individuals with intellectual disabilities. The federal government, in coordination with the CDC, has partnered with CVS and Walgreens in the Pharmacy Partnership for Long-Term Care Program, which will vaccinate people in these settings.

Are there side effects from the vaccines?

So far, no serious side effects have been reported. However, some people participating in trials have reported temporary reactions like sore arms, fevers and tiredness 24-48 hours after receiving the vaccine. As a result, vaccinations in prioritized settings, such as hospitals and long-term care facilities, may be staggered.

If two shots are necessary, how will people know when to get their second shot?

The Pfizer, Moderna and AstraZeneca vaccine (which is anticipated to be approved later) all require two doses given a set number of days apart. It is important to know when a person received the first dose of vaccine, and which vaccine they were given, to ensure they receive the second dose of the same vaccine at the right time. The shot you take, and when you need the second dose, is health information that is carefully managed to protect your privacy. North Carolina will use a secure data system called the COVID-19 Vaccine Management System (CVMS) to manage vaccinations. When a person gets a first dose, they will be given information on when to come back for a second dose and asked to make a second appointment. They will also be given information about which vaccine they got for their first dose and the date of that dose.

How much will the vaccines cost?

The COVID-19 vaccine will be available to everyone for free, whether or not you have health insurance. The federal government will be purchasing the vaccines.

Do people who have had COVID-19 still need to be vaccinated?

The CDC has not yet said whether people who have had COVID-19 should get a vaccine. There is currently not enough information to know if having had COVID-19 creates natural immunity or how long that may last. Early data suggests that natural immunity from COVID-19 may not last very long, but more information is needed to determine this time frame.

Will people who have been vaccinated still need to wear a mask and avoid close contact with others?

Yes. While experts learn more about the protection that COVID-19 vaccines provide under real-life conditions, it will be important for everyone to continue using all the tools available to us to help stop this pandemic, like the 3 Ws - wearing a mask, staying 6 feet apart whenever possible, washing your

hands, and limiting gatherings. Until more is known, receiving the COVID-19 vaccination and following the 3 Ws will offer the best protection from getting and spreading COVID-19.

Will people who have been vaccinated still need to be quarantined?

Experts need to understand more about the protection that COVID-19 vaccines provide before deciding to change recommendations on whether people who are vaccinated still need to be quarantined if they have been in close contact with someone who has COVID-19.